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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,740	03/27/2002	Xavier Nassif	1721-43	8255

7590

08/08/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,740

Applicant(s)

NASSIF ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

RESTRICTION

1. Applicant's amendment filed on 11/1/02 has been entered. Claims 5,9, 13 and 16-24 have been amended. Claims 1-24 are pending in the application.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-5, 17 and 19 drawn to polypeptide, vaccine composition.

Further restriction to one DsbA ORF (Open Reading Frame) Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

Group II, claims 6-14,16 and 18 drawn to DNA, vector and host cell and process of expressing polynucleotide.

Further restriction to one DsbA ORF Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

Group III, claims 20 and 24 drawn to an antibody and a therapeutic composition.

Further restriction to one DsbA ORF Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

Group IV, claim 21 drawn to a method for diagnosing Neisseria infection using peptide or antibody.

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Further restriction to one DsbA ORF Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

Group V, claim 22 drawn to a method for inducing immune response using polynucleotide.

Further restriction to one DsbA ORF Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

Group VI, claim 23 drawn to a method for inducing immune response using polynucleotide.

Further restriction to one DsbA ORF Or FhaB ORF Or FhuA ORF Or Rni5 ORF Or RTH17-Rth21 ORF Or TolC ORF required (see paragraph # 4).

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to a polypeptide and a vaccine composition, which is the first product. The special technical feature is the polypeptide, which is made up of amino acids. However, SEQ.ID.NO: 66/68/72/ corresponding to the TolC ORF of N.meningitidis is anticipated by the prior art sequence, Accession number: AF 121772. Therefore, there is no special technical feature exists in Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. The technical features of Groups II-III are drawn to DNA and antibodies that share no common structure, property and function because DNA is made of nucleic acids and antibodies are made of amino acid with specific binding property and specificity. The technical features of Groups IV-VI are drawn to methods having no common goals, no common method steps and use starting material that has no special technical feature such as polypeptide. Note that PCT Rule 13.2 does not provide for multiple products or methods within a single

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application. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Group II-III inventions are not present in the Group I claims, unity of invention is lacking.

4. For each group of inventions I-VI above, restriction to one of the following Open reading frame (ORF) DsbA ORF (SEQ ID NO: 1 –26) Or FhaB ORF (SEQ ID NO: 27 –28) Or FhuA ORF (SEQ.ID.NO: 29-52) Or Rni5 ORF (SEQ.ID.NO: 53-54) Or RTH17-Rth21 ORF (SEQ.ID.NO: 55-64) Or TolC ORF (SEQ.ID.NO: 65-90) is also required under 35 U.S.C. 121 and 372 because SEQ.ID.NO: 66, 68 and 72 TolC ORF of N.meningitidis is anticipated by the prior art Accession number: AF 121772. The disclosed sequence is identical to SEQ.ID.NO: 66, 68 and 72 and the polynucleotides (SEQ.ID.NO: 65, 67 and 71 are 99.8%, 99.6% and 100% identical respectively) encoding them. They lack the same or corresponding special technical features and thus there is no special technical feature exists among ORFS and therefore, unity of invention is lacking. Therefore, election is required of one group of inventions I-VI and one of ORF for examination.

For example: If applicant Group I polypeptide then he has to elect one ORF such as DsbA ORF. Applicant is advised to indicate clearly the sequence identification numbers that correspond to elected ORF such as SEQ ID NO: 2/4/6/8/10/12/14/16/18/20/22/24/26 for DsbA ORF.

5. Applicant is required, in reply to this action, to elect ONE group and identify the SEQ.ID.NOs corresponding to ONE ORF to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.
8/5/03

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